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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region III
841 Chestnut Building
Philadelphia, Pennsylvania 19107

SUBJECT: Valley Forge General Hospital Site Investigation

DATE: May 6, 1991

FROM: Reginald F. Harris, Toxicologist RH
Technical Support Section (3HW15)

TO: Lisa M. Cunningham, SIO
Federal Facilities Section (3HW26)

SUMMARY

Upon review of the Site Investigation Report for the Valley Forge General Hospital Site, the letter submitted by Karen Neely expressing her concerns about the quality of this Site Investigation, and other information related to the site; it was determined that the Site Investigation was carried out in accordance with Agency policy. The quality control measures for the sampling and analytical procedures were satisfactory, sampling and analytical techniques were appropriate, and based upon the scope and intent of this investigation the conclusions drawn were valid and the assessment of the site was properly conducted.

Ms Neely's concerns related to the toxicological and risk assessment aspects of this Site Investigation will be addressed individually below, followed by a toxicological review of the site.

SUPPORT

QUALITY CONTROL

The first area of concern in Ms Neely's letter is quality control. A review of the data summary tables, laboratory analysis, and the comments found in the text of this document revealed a high level of quality control carried out in accordance with the policy of this Agency. Ms Neely stressed a concern based upon the contamination of the method blanks by several contaminants. Method blanks are prepared to determine what contamination, if any, is contributed to the samples due to the methodology used in sample collection and preparation. It seems to be her feeling that all of the analytical data is invalid due to this contamination. In actuality, the nature of this contamination is such that it has no bearing on the quality of the data generated, or on the analytical

results. The contamination of the method blanks is due to the common laboratory contaminants methylene chloride, acetone, bis-(2-ethylhexyl)phthalate, di-n-butyl phthalate, and di-n-octylphthalate. This contamination is not a cause for concern. Contamination of this type is commonly seen in these analytical procedures. The contamination may be due to the chemical substances used to clean and prepare equipment, may be the result of procedures employed to extract constituents from sample materials, or may be due to minute amounts of substances that are components of sampling equipment or analytical apparatus being introduced into the samples through field collection procedures or laboratory manipulation. The quantities of these substances being discussed are in the low parts per billion (ppb) range and have no adverse effects on human health. Methylene chloride is a common laboratory solvent used for cleaning and extraction. Acetone was used to decontaminate the sampling equipment in the field, and the three phthalates are plasticizers that are common sampling and laboratory artifacts. All of these substances are commonly detected as laboratory contaminants at low levels such as those noted in this Site Investigation (SI). It should be noted to the credit of those responsible for the preparation of this SI, that the explanation for the source of this contamination was cited in the SI on pages 23 and 24. These contaminants were evaluated in the Toxicity Assessment in an effort to be most conservative and protective of human health, as well as to satisfy the concerns of the public. The SI was carried out with extreme care and concern for those impacted by the site. I found no cause for alarm or increased risk to the public due to this blank contamination. All data was properly documented, validated, and quality control measures at the appropriate level were utilized.

Ms Neely stated that it was not appropriate to use aqueous blanks for soils in her letter. She felt that the blanks should be of the same matrix as the sample being collected. For some types of analyses this may be an appropriate approach, in this case it is neither possible or practical. Blanks in general are clean samples, free of contaminants. In order to match the matrix a sample would need to be composed of the same constituents as the samples in question in comparable proportions, and would need to be free of contaminants of concern. The technical problems presented are obvious. Sand would not be appropriate as a matrix since its composition would differ greatly from the soil, thus causing certain matrix effects that may interfere with the analysis. Additionally, seeking a matrix match would not be cost effective and would provide no better results

than the use of the aqueous blank. The purpose of the blanks in question must also be considered. The purpose of the trip blank is to determine if any contamination is being contributed to the samples during handling and in transit. Method blanks determine if any contamination is being contributed during the handling associated with the procedural manipulation of samples. Aqueous blanks are more than adequate for this purpose. The methods utilized are in accordance with the guidance provided by this Agency, and are sound laboratory practices used routinely in Remedial Investigations (RIs), in SIs, and in all other investigative and response activities conducted by this Agency. It would be unreasonable and technically impractical to attempt to prepare the type of blanks suggested by Ms Neely.

With reference to the statements concerning the split and duplicate samples, it is noted that two split samples were outside of the acceptable analytical range. This simply means that the results of the analysis of two portions of the same sample fell outside of the range of quantitative agreement. In one instance lead from incinerator stack soot was reported in one sample at 1240 ppm and in the split at 7620 ppm. In the other instance, toluene was reported in one composite soil sample at 21 ppb and in the split at 570 ppb. In reviewing these results, it is noted that the soil samples in question were composites that may not have been thoroughly homogenized, or quite possibly the samplers may have encountered a "hot spot" (an isolated area of higher concentration of a contaminant) that may have resulted in some material with much higher levels of the contaminant getting into the sample. The soot sample may not have been completely homogenized, and may have contained some pieces of high concentration lead. This occurred in only two splits, and did not effect the results. Neither split value represented the maximum contaminant value reported for the given medium, and had no bearing on the values used to assess risk. This situation did not result in any false positive or false negative analytical results that could have effected the outcome of the assessment of the contamination on the site or altered the assessment of the threat to human health. This minor analytical occurrence therefore does not invalidate the data.

INADEQUATE SAMPLING / SAMPLING PROCEDURES

Ms Neely suggests that one round of sampling is not enough to make any definitive conclusions, and that it

can only suggest that there is or is not contamination. In reviewing the scope of the investigation and the intent of this SI, it seems that all of the intended objectives of this investigation were met. This SI was never intended to be a final investigation that would furnish a definitive answer. This investigation was a screening study intended to identify the contaminants of concern for further study, to evaluate the areal distribution of contamination around the site, and to determine if the possibility existed that an imminent danger to human health was present due to the contamination at this site. One round of sampling has identified the possible contaminants of concern, determined the areal distribution of these contaminants on-site, and has assessed risk to the public based on the most conservative worst-case scenario possible in order to be protective. By using an extreme worst-case scenario, the COE has afforded the public greater protection by overestimating the risk. COE has clearly stated that additional study is required in order to further characterize the site related contamination, and to more precisely define the risk to human health.

The question of off-site investigation is best addressed by saying, as indicated in the SI, further investigation is required at this site. There are of course questions concerning the extent of contamination which can not be answered by a study such as the one undertaken in this SI, therefore additional investigation is both expected and prudent. The idea of using the analytical data from the inside of the incinerator stack as an exposure scenario was designed as a screening tool to indicate the possibility of a risk to the public due to exposure to the contaminants emanating from the incinerator. It is understood that the contaminants in the stack would be at a concentration several orders of magnitude greater than those to which the public would be exposed, and that dilution of the contaminants would occur through their dispersion from the stack during the incinerator's operation. Demonstrating that if no unreasonably high risk existed for exposure to levels of contaminants inside of the stack, then no unreasonably high risk would exist for the public that would be exposed to the contaminants at much lower concentrations, was a reasonable effort within the limits of this study to assess the threat posed by the site to the public in the vicinity. Of course this was not intended to provide a definitive answer, and does not eliminate the need for additional investigation or off-site sampling. Given the conservative nature of the exposure scenario, it is unlikely that any imminent threat to human health exists. However, off-site sampling should be a part of any

further investigation. In addition, the exposure scenario used requiring an adult of 70 kg body weight to ingest 100 mg of the contaminants from the inside of the stack everyday for a lifetime produced a contaminant dose which is many orders of magnitude greater than any exposure reasonably possible. Needless to say, no one will reasonably be expected to be exposed so severely to these contaminants.

Ms Neely repeated her concerns about the method blank contamination and stated that she felt the laboratory analytical techniques were of poor quality. As mentioned earlier, the method blank contamination issue was more than adequately address in the SI. The contamination was due to common laboratory contaminants (see pages 23 and 24), which did not effect the quality or the accuracy of the laboratory analyses. This contamination is not representative of poor laboratory practices as is stated in Ms Neely's letter. As to the question of the degree of contamination, all levels were within the range commonly seen in laboratory analyses of these types of samples.

Ms. Neely pointed out that no dioxin analyses were preformed on "surface" soil samples below three inches despite its presence in soil boring samples up to 7-9 feet. She then adds that the deepest soil borings were not analyzed for dioxins. First of all, dioxins are contaminants that will strongly bind to soils so it is most important to evaluate their association with the surface soils with which the public may reasonably come into contact. Assessment of the top three inches of the soils was both reasonable and scientifically prudent. At this time it is not important that we define the vertical extent of contamination due to dioxins. It is most important that the areal distribution of dioxins be defined in order that the risk to humans through incidental ingestion of the contaminant (the most significant pathway of human exposure in this instance) could be assessed. The contaminants need to first be located before it is determined how far they may extend into the subsurface. There is little chance that a member of the public at large would be exposed to dioxin contamination at 7-9 feet below the soil's surface.

The letter points to an overall inconsistency in the analytical procedures. It points out that all split samples were not analyzed for the same analytes (PCBs and pesticides were not analyzed in samples below three inches deep), and that only VOCs were analyzed in the trip blanks. PCBs and pesticides bind very strongly to soils and are very insoluble in water, therefore they

tend to stay were they are deposited, and as with the dioxins the risk of incidental ingestion is being assessed as the most significant exposure pathway for humans. Therefore, considering the type of investigation being undertaken this analytical approach is valid. The sampling and analysis is viewed as being both consistent and technically reasonable. In cases where all types of analyses are not preformed in all media, there are very good reasons. For example, it is not prudent to sample for volatile organic compounds in an incinerator stack. These compounds readily volatilize in air, needless to say they would not reasonably be found in an incinerator. Trip blanks are prepared to determine if any contributing contamination occurs in sample handling and transport. Due to the chemical and physical properties of VOCs, it is appropriate that trip blanks be analyzed for their presence. Thus, what has been perceived as a weakness in the analytical protocols according to the Neely letter, clearly shows the technical expertise and thorough understanding of the chemical and physical properties of the chemical constituents in question.

ADDITIONAL COMMENTS / QUESTIONS

Ms. Neely suggests that the objectives of the investigation were inadequate in that they focused too much on the landfill and not on the entire site. The focus of the investigation was threefold, to identify the contaminants of concern, to define the areal extent of contamination on-site, and to determine if there was an immediate threat to human health posed by the contamination on the site. These objectives, as previously stated, have been clearly met. The nature of the sampling was such that it characterized the contaminant levels in all on-site media, and addressed the dispersion of those contaminants around the site. Soil borings were taken from a number of areas around the site. Sediment samples were taken from the North and South streams. Surface soils were sampled from the tennis courts, soccer field, playground, ball field, near Township Road, near a monitoring well, and many other locations. The incinerator was sampled at the top, at the middle, and near the bottom. Groundwater was collected from a number of locations. In all, the sampling of the site was thorough. The sampling plan and assessment methodology allowed for a best estimate of the exposure to contaminants based on a worst-case scenario which is far more conservative than Agency guidance defines. As pointed out in the SI, this assessment evaluates exposures that are far more severe than what is actually seen by the exposed human population at this site. It is felt that the sampling done in this Screening SI defines

the total area of the site in question as well as can be expected considering the scope and intent of this study.

Ms Neely states that the report failed to meet one of its objectives in that it indicated that no further action is required. This document characterizes the contaminants of concern, describes the contaminated media, and recommends that additional study is required. Based upon the procedures for listing and evaluating a site, and the results of this study, it is appropriate that further study was recommended by the COE. No emergency remedial action was recommended since no imminent danger to human health was identified by this study. It must be pointed out that during the April 19,1991 meeting with Community Leaders, COE outlined the scope of work for removal action and the Remedial Investigation/Feasibility Study for the Valley Forge General Hospital Landfill. As stated by Ms Neely, it is true that no imminent danger does not mean no danger. There may be some risk to the public, however that risk must be determined through a focused investigation. The SI indicated that no immediate risk requiring emergency removal exists at the site, and there appears to be no high level of risk, but as stated previously further study and evaluation is needed.

In answer to the question as to why groundwater was sampled, the sampling was necessary because over 7600 residents in the area with private wells rely on groundwater as their drinking water source. In addition, a number of other residents in close proximity to the site are serviced by public supplies that use groundwater as a part of their supplies.

The terminology "Regional Background" is used in this document in reference to a characterization of elements at their typical levels as they are found in soils in the Eastern United States. The information is gathered by the U.S. Geological Survey that surveys the soils around the United States, characterizing them by compositional makeup. This information comes from "Elemental Concentrations in Soils and Other Surficial Materials of the Conterminous United States," by Shacklette and Boerngen for the U.S Geological Survey.

While lead from auto exhausts is mentioned on page 23 as a possible source of lead contamination on-site, it is not the only source mentioned. The document mentions the fact that "the area was mined for lead, iron, zinc, and some copper." The document goes further to say, "smelting of the ores would have provided a source for the lead found in the surficial soils." It must be acknowledged

that these explanations are offered as possibilities and not definitive answers as to the sources of contamination, and no further meaning should be read into the statements. Many millions of tons of lead emissions were deposited in the air by auto emissions up until the phasing out of leaded gasoline began in 1973, and unknown quantities of lead bearing ores were mined in the area. These by no means are being suggested as the only sources of the bulk of the lead contamination at the site, but rather are being suggested as contributing factors.

Ms Neely questions the mention of dieldrin as having been detected in soils and in groundwater in the area, and she feels that since this contaminant is not naturally occurring, it is not appropriate to characterize this contamination as background. First of all, as a part of the site or area history it is important to document the apparent use of dieldrin in the area as a pesticide. Since dieldrin was only detected in one sample on-site and in two groundwater samples, and there is no evidence of its use at the site; it is proper to include this information relating to its use and distribution in the area. The widespread use of the pesticide in the area may indeed be the source of this contamination, since the levels of contamination reported are within the range seen in other investigations in the region.

In reference to the comments concerning the length of the SI and the explanatory portions of the document, it should be noted that this SI has been prepared in accordance to Agency guidance, and that all information included is of relevance to the investigation.

ENDANGERMENT ASSESSMENT

A complete evaluation and review of the risk assessment aspects of this document was conducted by this reviewer. The report used a worst-case exposure scenario as the basis for the assessment of risk. In other words, the highest concentrations of each chemical of concern in each of the various media was used as the basis for exposure calculation. The individual exposure parameters used in the scenarios were also worst-case. In the scenarios, the absolute maximum exposure durations and the exposure routes which would be expected to be the most significant sources of exposure to the contaminants were used for risk estimation. The scenarios were so overly conservative that no one could possibly be expected to be exposed so severely. It must be pointed out, that these overly conservative risk estimates overestimate the actual risk to the public by several orders of magnitude, thereby decreasing the possibility

of there being any portion of the target population being left unprotected by such conservative risk estimates. It is therefore more desireable to overestimate risk, as in this instance, then to underestimate risk and leave portions of the population unprotected.

The most significant pathways of exposure are addressed by this assessment. Additional pathways exist, but were not addressed for the purpose of this investigation, since it was designed as a screening activity, and their contributions to the total risk were small. Extensive pathway development and characterization would be a part of a more focused study. The possible contaminants of concern are identified, and the chemical properties of the contaminants in question are listed, with the exception of lead. Lead was not identified as a Group B2 (probable human carcinogen), as recognized by this Agency. The IRIS database and the Health Effects Assessment Summary Tables (HEAST) do not list a cancer potency factor for lead at this time, however an interim potency factor for lead developed by a Regional toxicologist, 4.0E-02 (mg/kg/day)-1, is used in this review for the purpose of assessment of risk. The Corrective Action Level (CAL) calculations used in this SI should be replaced with Hazard Index and Increased Cancer Risk calculations in any future assessment of risk for this site. The conclusions drawn based upon the CAL evaluation were in agreement with those drawn based upon Hazard Index and Increased Cancer Risk criteria, however the procedures and evaluation criteria found in Risk Assessment Guidance for Superfund (RAGS) should be used in the future. Editorial errors were noted in Table 7, the code "NA" was used for dioxins/furans in groundwater instead of "ND". A second set of editorial errors were noted on page 31 of the document. The units of concentration for lead should be "mg/kg" instead of "ug/L".

The combined increased cancer risks for the incidental ingestion of 100 mg per day of the contaminated media by a 70 kg adult each day for a lifetime were calculated, as outlined in the SI. Slope factors for the contaminants of carcinogenic concern were taken from the IRIS database and HEAST in all cases expect for lead. As previously stated, the IRIS database and HEAST have no listed slope factor for lead. A Regional toxicologist has calculated an interim slope factor for lead which the reviewer has used for the evaluation of risk at this site. This interim slope factor, as previously stated, is 4.0E-02 (mg/kg/day)-1. Using the worst-case scenario exposures outlined in the SI, the combined increased cancer risks due to the ingestion of contaminated soils originating

from soil borings were calculated. As calculated by the reviewer, they were 5.0E-05 excluding lead from the calculations, and 2.0E-04 if lead is included. The combined increased cancer risks for the incidental ingestion of contaminated sediments were 1.2E-05 excluding lead, and 2.6E-05 with lead. The combined increased cancer risks for the incidental ingestion of incinerator soot are calculated with and without lead being included as 2.5E-03 and 2.2E-04, respectively. The combined increased cancer risks calculated for the ingestion of contaminated groundwater are 1.5E-04 and 1.2E-04 for risk calculations done with and without the inclusion of lead, respectively. The combined increased cancer risks calculated for the incidental ingestion of contaminated surface soils are calculated as 9.2E-05 with the inclusion of lead, and 8.2E-05 without its inclusion. The increased cancer risk calculations are, as stated previously, extremely conservative. The use of the maximum contaminant levels for the calculation of exposure and risk values greatly overestimates risk, as does the use of maximum exposure duration values in exposure estimation. It is doubtful that any receptor will be exposed to concentrations of contaminants approaching those used in the estimation of risk for this SI, they should actually be much lower. The soot ingestion scenario which is used to characterize the exposure to contaminants from the incinerator is probably the most conservative exposure scenario of them all, and overestimates risk by several orders of magnitude.

Noncarcinogenic effects are assessed by the use of the Hazard Index calculation. The Hazard Index (HI) is derived by calculating the daily intake of the contaminant, and dividing it by the Reference Dose (RfD) for that substance. If the HI value resulting from this calculation exceeds one (1), deleterious noncarcinogenic health effects may be expected. HI values of greater than 1 were calculated for lead, cobalt, antimony, and cadmium in at least one medium each. Again, the actual exposures and consequent risks are probably much lower.

The toxicological assessment notes that several contaminants identified at this site are present at levels of concern. Those contaminants are chromium, mercury, beryllium, lead bis(2-ethylhexyl)phthalate, dieldrin, benzo(a)pyrene, dioxins/furans, and aroclor 1242 (PCB). Further consideration may be required for antimony, cadmium, cobalt, and pyrene. It should be noted that due to the significant overestimation of risk in this document, further characterization of these contaminants is necessary. Upon further characterization, using more realistic exposure assessment criteria, it may

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be found that some of these contaminants exist at levels for which there would be no cause for concern.

In summary, the SI has characterized the possible site contaminants, defined the areal distribution of on-site contamination, and determined that no imminent threat to human health exists within the limits of the data obtained and evaluated in this investigation. There may be some increased cancer risk due to the exposure of on-site receptors to contaminants of carcinogenic concern, and some possibility exists that receptors may be impacted by exposure to contaminants exhibiting noncarcinogenic effects. However, these deleterious health effects are based upon chronic exposure to on-site contaminants at levels and for durations, which for all practical purposes will never be encountered by receptors at the site. From the standpoint of risk assessment, the conclusions drawn are reasonable, the sampling procedures and strategies are sound, and the level of technical skill adequate. Further investigation of this site is appropriate. At some point in time a more defined investigation that will characterize the risk to human health and the environment more precisely and that characterizes the extent of both on and off-site contamination should be conducted.

It is suggested that if desired, Ms Neely be allowed to attend the Regional Course in Basic Risk Assessment or speak with the personnel involved in this review, in order that she may have the opportunity to better understand the risk assessment process.

cc: Roy Smith
Henry Sokolowski